



# Academy of Medical Psychology

May 7, 2004

RE: DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration 21 CFR Chapter I  
Docket No. 2004N-0115

The Academy of Medical Psychology supports the ability of United States citizens to purchase medications directly or imported from other countries. The Academy is comprised of licensed clinical psychologists with doctoral degrees. In addition, members are required to have completed 300 hours of postdoctoral psychopharmacology training meeting the standards of the American Psychological Association, have completed a postdoctoral Fellowship of 1500 hours, and have passed a National Examination in Psychopharmacology. The focus of the Academy has been on public access to high quality mental health treatments consisting of pharmacotherapy, psychotherapy or a combination of both treatment modalities. We are pleased to inform you that on May 6th the Governor of Louisiana signed a bill granting prescriptive authority to specially trained psychologists as fostered by our Louisiana affiliate organization.

Our support for purchase of imported medications or directly from outside the United States comes in part from a recent Harris Poll sponsored by PacifiCare Behavioral Health and Psychology Today magazine. This poll reports that mental health treatment is an important health care need since 27% of those surveyed had received such services in the last two years. Of those receiving mental health treatment, estimated to be 59 million, 81% had taken a prescription medication for their condition, with 47% using medication alone, 34% using a combination of medication and psychotherapy, and with 19% receiving psychotherapy alone.

On the other side of the question of the need for care, 37% (an estimated 24 million people) in this survey reported experiencing sufficient distress to warrant specialty mental treatment did not receive this specialty care. Of those needing care but not receiving it, 39% reported mental health care was too expensive, and 26% were concerned about the lack of health insurance coverage. These estimated 24 people, representing about one in 10 of the general adult US population eligible to vote, plus the estimated 50 million people receiving psychotropic medications constitutes a major market for the pharmaceutical industry. The high cost of psychotropic medications purchased in the United States in comparison to the lower cost of these same medications purchased in Canada is the equivalent of an extra tax burden to the mental patients we serve, especially in underserved and rural areas. Therefore we support the ability of US citizens to purchase the medications they need from Canada and other sources of pharmaceuticals.

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We believe it is patently unfair to restrict citizens from purchasing medications from outside the United States when pharmaceutical companies can outsource the manufacture of their medications to other nations and import them for sale in the United States. While this outsourcing may reduce the cost of imported medications sold in the United States, the high mark up of the cost of medications to a captive population is unconscionable when these same products are available at less cost elsewhere. The present Medicare drug plan, providing discounts on medications, is still more costly to our patients than their direct purchase of psychotropic medications from Canada. We have not received any reports from our patients that the purchase of medications from Canada has reduced the effectiveness of treatment.

A public policy that artificially inflates the cost of mental treatment by restricting purchase of psychotropic medications to the United States suppliers is contrary to common sense. When there is a large unmet need (37%) of the population surveyed and a high percent of those reported that mental health treatment is too expensive and/or they do not have health insurance, restriction of purchase to more costly sources of medication is not in the public interest. Such a policy would effectively deny outpatient care to the poor and uninsured people needing mental care. It would force these populations to seek more costly care from the emergency rooms of general hospitals or the mental wards of state operated facilities. It is also reported there is an increased number of visits to emergency rooms of general hospitals by uninsured patients due to reductions in their insurance coverage. Mental conditions are one of the conditions least often covered by insurance contracts. It is estimated that up to 70% of patient visits to general health clinics are prompted by psychosocial factors and can be prevented by prompt psychological interventions. With high use (81%) of psychotropic medication for mental conditions it is essential we have a rational policy regarding the purchase and importation of less costly medications.

Thank you for the opportunity of submitting this information for considerations in your hearings.

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MN/hb

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